NRx Pharmaceuticals (Nasdaq: NRXP) Reports Update from the FDA Revising Previous Major Amendment to a Minor Amendment for Preservative-free Ketamine

September 15, 2026

- Abbreviated New Drug Application (ANDA) Amendment related to the drug vial for preservative-free ketamine has been reclassified from a Major Amendment to a Minor Amendment.
- FDA has revised the Generic Drugs User Fee Act (GDUFA) Goal Date to November 10, 2026.

WILMINGTON, Del., Sept. 15, 2026 (GLOBE NEWSWIRE) -- **NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", "NRx" or the "Company"),** a clinical-stage biopharmaceutical company, today announced that it has received a written communication from the Director of Regulatory Operations of the FDA Office of Generic Drugs advising the Company that the amendment to its Abbreviated New Drug Application (ANDA), previously classified as a Major Amendment, has been reclassified as a Minor Amendment.

The acknowledgement letter revised the GDUFA goal date to November 10, 2026, citing that the reclassified amendment will not require a substantial expenditure of FDA resources.

“On behalf of our patients and our shareholders, we are deeply appreciative of the speed with which FDA's leadership has moved to advance the approval process of this strategic, drug shortage product,” said Dr. Jonathan Javitt, Chairman and CEO of NRx Pharmaceuticals.

About NRx Pharmaceuticals, Inc.

NRx Pharmaceuticals, Inc. (www.nrxpharma.com), is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal depression, chronic pain, and PTSD. The Company is developing NRX-100 (preservative-free intravenous ketamine) and NRX-101, (oral D-cycloserine/lurasidone). NRX-100 has been awarded Fast Track Designation for the treatment of Suicidal ideation in Depression, including Bipolar Depression. NRX-101 has been awarded Breakthrough Therapy Designation for the treatment of suicidal bipolar depression. NRx has filed an Abbreviated New Drug Application (ANDA), and initiated a New Drug Application filing for NRX-100 with an application for the Commissioner's National Priority Voucher Program for the treatment of suicidal ideation in patients with depression, including bipolar depression.

About HOPE Therapeutics

HOPE Therapeutics, a subsidiary of NRx Pharmaceuticals (Nasdaq: NRXP), is a provider of advanced psychiatric and neurological care, specializing in evidence-based treatments for major depressive disorder, anxiety, and other complex neurological conditions. Operating out of state-of-the-art clinics, HOPE Therapeutics focuses on improving patient outcomes through the application of modern medical technologies and clinical practices. For more information, please visit www.hopetherapeutics.com.

About ZETA SURGICAL

ZETA SURGICAL is redefining the standard of care for image-guided surgery and targeted neuro-therapeutics. Its navigation and robotics platform applies advanced artificial intelligence and computer vision to enable high-accuracy image guidance across virtually any point of care in minutes, unlocking less invasive and more precise targeted therapies. The Zeta Navigation System, Zeta TMS Navigation System, and Zeta TMS Robotic System are cleared by the FDA and commercially available in the United States. For more information, please visit www.zetasurgical.com.

Media Contact -- media@zetasurgical.com

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The information contained herein includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "look forward," and other similar expressions among others. These statements relate to future events or to the Company's future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. The Company has reported regulatory milestones as they have been achieved but has not predicted the outcome of any future regulatory determination. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond the Company's control and which could, and likely will, materially affect actual results, levels of activity, performance or achievements. Any forward-looking statement reflects the Company's current views with respect to future events and is subject to these and other risks, including uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy, and, among other things, liquidity. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's most recent Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. Except as may be required by applicable law, the Company assumes no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, whether as a result of new information, future events or otherwise.

For further information:
Brian Korb
Managing Partner, astr partners
(917) 653-5122
brian.korb@astrpartners.com